VERTICAL TRANSMISSION RATE OF HIV AMONG ACCEPTERS OF PREVENTION OF PARENT TO CHILD TRANSMISSION (PPTCT) INTERVENTIONS IN KANIYAMBADI BLOCK AND CHAD HOSPITAL

DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENT OF THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY FOR DEGREE OF M.D. BRANCH XV - COMMUNITY MEDICINE EXAMINATION TO BE HELD IN MARCH 2008

CERTIFICATE

This is to certify that "Vertical transmission rate of HIV among accepters of Prevention of Parent to Child Transmission (PTCT) interventions in Kaniyambadi block and CHAD hospital" is a bona fide work of Dr. Clarence James Samuel in partial fulfillment of the requirements for the M.D. Community Medicine examination (Branch XV) of The Tamil Nadu Dr. M.G.R. Medical University to be held in March 2008.

GUIDE:

Dr. Jasmin Helen Prasad,
Professor,
Community Health Department
Christian Medical College, Vellore.

HEAD OF DEPARTMENT:

Dr. Jayaprakash Muliyil
Professor & Head,
Community Health Department,
Christian Medical College, Vellore.

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1. INTRODUCTION AND JUSTIFICATION

In 2006 the Joint United Nations program on HIV/acquired immunodeficiency virus (AIDS) estimated that globally there were approximately 39.5 million people infected by the Human Immunodeficiency virus. Of this, 2.3 millions were children under 15 years of age.[1] Every year between 570,000 and 740,000 children are estimated to be newly infected with HIV-1. An estimated 420,000-580,000 of these children die every year.

India has been home to over 3.36 million HIV-infected women of child-bearing age[2] and 160,000 infected children (aged 0–15 y).[2, 3] Mother to child transmission is responsible for nearly 90% of pediatric HIV cases. 2% of all HIV cases in India are among children. [3] The parent to child transmission rate is between 30-40 percent without intervention. In Maharashtra Kumar et al reported a transmission rate of 48%, while Dongaonkar et al showed 36% [5]. Sero-prevalence rate in Tamil Nadu was 1.6 percent in 2001 among the antenatal women but has fallen to 0.6% in 2006. Assuming 25 million births(4) per year in the country and the sero-prevalence rate among pregnant women of 1% and vertical transmission rate of 30%, we would expect 75000 HIV infected neonates born to HIV positive mothers every year. Of an estimated 650,000 mothers who underwent screening about 2700 were tested as HIV positive.[5] There have been many recent advances in preventing vertical HIV transmission. The use of anti-retroviral, caesarian sections and formula feeding (as a replacement for breastfeeding) have been shown to be efficacious in reducing the risk of transmission.[6]

Malnutrition in its many forms persists in all countries of the world, but it is worse in developing countries where an estimated 174 million children under five years of age are malnourished, as indicated by low weight for age. [7] India with its abundant and favorable natural and human resource potential, has consistently reported unacceptably high levels of child hood malnutrition by the National Family and Health surveys (NFHS III), with 38 – 39 % of the children below three years of age stunted, 45-51% underweight and 16-19.8 % wasted[8]. It has been accepted that malnutrition causes under-development of physical and mental of abilities. This has serious ramifications for the countries future; a nation populated by citizens who have failure to achieve their full potential was easily preventable. This problem is further compounded by the HIV/AIDS pandemic. The devastating impact of HIV is felt by infected individuals and those who are economically or emotionally dependent on them. HIV/AIDS increases the vulnerabilities of the child with the incapacitation or loss of one or both parents. The changes in socio economic status often lead to unmet basic needs thereby increasing the risk of malnutrition and higher susceptibility to illness.

The community health department of Christian Medical College has been providing maternal and child health services to the residents of the Kaniyambadi block for the last forty years. Since 2002 the antenatal care includes the screening for HIV and HBsAg. The positive are followed up at the secondary care level with recommended protocols to prevent mother to child transmission. This study was under taken to calculate the rate of vertical transmission in Kaniyambadi block after 5 years of intervention, the acceptance and compliance to the PPTCT protocols and to study the nutritional status in this high risk group.

2. AIMS AND OBJECTIVE

AIMS:

1. To evaluate the effectiveness of the Prevention of Parent to Child Transmission of HIV program (PPTCT) run by CHAD hospital.

2. To study the health and morbidity pattern of children born to HIV positive mothers

SPECIFIC OBJECTIVES:

1. a) To calculate the prevalence of HIV infection among antenatal women in Kaniyambadi block, and CHAD antenatal Clinic from May 2002 to December 2006

   b) To study the compliance of HIV positive women with the PPTCT protocol

   c) To determine the effectiveness of the CHAD program in reducing vertical transmission.

2. a) To compare the morbidity pattern of children born to HIV positive mothers with that of children born to HIV negative mothers.

   b) To compare the nutritional status of children born to HIV positive mothers with that of children born to HIV negative mothers.

3. REVIEW OF LITERATURE

3.1 Epidemiology

3.1.1 Magnitude of the problem of HIV infection

The Human Immunodeficiency virus was first identified as the causative agent for the Acquired Immunodeficiency syndrome in 1981. In the last twenty five years, the AIDS pandemic has claimed to 20 million lives globally.[1] Globally, of the 39.9 million people living with HIV in 2006, an estimated 2.3 million are children under 15 years. Of the 4.3 million newly affected by the virus in 2006, children less than the age of 15 were 53000. There were a total of 2.9 million deaths due to HIV in 2006 of which 13.2 percent occurred in children. It is estimated that 90% of HIV infected persons live in the developing countries. Every day, about 14,000 new HIV infections occur worldwide [9]. More than 95% are in low and middle-income countries; Almost 2,000 are among children under 15; Over 40% occur among women; and more than 40% are among young people aged 15 to 24. [10]

3.1.2 Magnitude of HIV in India

In 1986, India's first case of HIV was identified in a commercial sex worker from Madras by researchers in Christian Medical College, Vellore and Madras Medical College, Madras. India has had since then a sharp increase in the estimated number of HIV infections. The variation in prevalence and spread of HIV in different parts of the country is as diverse as the societal patterns between its different regions. Transmission being mainly heterosexual in some regions, whereas injecting drug use is the chief mode of transmission in some other region.

In India an estimated 5.2 million people are HIV infected as on December 2005, second only to South Africa. This gives an adult prevalence of HIV infection in the country as 0.91%. One of every six new HIV infections occurs in India. Every minute two Indians become infected by HIV Out of total HIV infections, 38.4% were females, and 57% were in rural areas. Out of the total, 59,007 were estimated to be children. In the year 2005, positivity among antenatal women in rural areas was 0.93%.[5] Overall, the average prevalence rate of HIV among adults in India is about 0.9% and it accounts for 10% of global HIV burden and 65% of that in south and south-east Asia.

The HIV epidemic has reached an important threshold in India; the type 4 pattern where the infection shifts from the highest risk group- (commercial sex workers, homosexual men, drug users etc) to the bridge population(clients of sex workers, STD patients, migrant population, population in conflict areas and partners of drug users) and then onto the general population. This occurs when the prevalence in the highest risk group reaches 5%.[11] Indian women who are already overburdened with high maternal mortality and limited access to health care would become further victimized by the feminization of the HIV epidemic. Indian women endure high rates of many other health problems, including the world's highest rates of cervical cancer, which would be expected to increase further due to HIV infection. At least 500,000 Indians have already died of HIV-associated illnesses and most of these deaths have occurred in the past 5 year.[12] HIV-associated morbidity and mortality puts an increasing, costly burden on public and private medical care systems, which are already coping with major challenges.

3.1.3 Mode of transmission

3.1.3.1. Sexual transmission:

Heterosexual transmission is the most common mode of transmission in India. Unprotected sex with an infected man or woman is the commonest route of transmission. NACO reports that sexual transmission accounts for 79% of HIV infection.[5] Heterosexual transmission is assumed to be the primary route of infection, because homosexuality is considered rare and generally not openly discussed. Many homosexual men will marry women to adhere to cultural norms and to have children, concealing their true sexuality. Women are more vulnerable to HIV infection because of larger surface area exposed. Decreased amount of mucus forms a less efficient barrier in the genital tract in adolescent girls making them more prone to HIV infection.

3.1.3.2. Blood Borne

The HIV virus is transmitted by contaminated blood and is affected by the quantity of the infected blood. Blood transfusions have a higher risk of transmission compared to needle stick injuries etc. Intravenous drug users- (IVDU) are at greater risk of the infection because of the repeated exposure. In 2005 the HIV prevalence among injecting drug users in as 10.16% in India.[5]

3.1.3.3. Vertical transmission- parent to child transmissions

This is the transmission of the HIV virus from an infected mother to her baby through any mechanisms or methods of transmission during or after pregnancy. HIV prevalence was >1% among antenatal mothers in 95 districts, including 9 districts in the low prevalence states. Similarly, HIV prevalence was >10 % in 34 STD sites across the country, indicating multiple heterogeneous

epidemics.[11] The multiple heterogeneous epidemics around the globe have different vertical transmission rates. In developed countries, it is between 14% to 33%[13] while in developing countries it is higher up to 43%[14, 15]. Within India too, due to inherent economic diversity vertical transmission rates range from 24% in Mumbai [16] to as high as 48% amongst tribal women.[17] There very few reports of pediatric HIV-2 infections from mother to child suggesting that there low perinatal transmission of HIV-2 as compared to HIV-1. Incidentally, the sero-prevalence of HIV-2 in India appears to be low with a probability of still lower prevalence amongst pregnant women. [3]

3.1.3.3.1The probability of transmission During Pregnancy:

25%-35% of total transmission takes place, during the antepartum period mainly during the late pregnancy.[18] Transmission during delivery (intrapartum) is responsible for around 70% - 75% of total cases. The postulated mechanisms are micro transfusion from constant massage the placental bed gets from uterine contractions and exposure of the baby's mucocutaneous surface to maternal blood and cervical secretions.

3.1.3.3.2 The probability of transmission after delivery:

Breast-Feeding (BF) accounts for 5-15% of infants getting infected after delivery. Associated breast abscess, cracks in nipple, mastitis and mixed feeding can add to the risk of transmission. Transmission also varies depending on the duration of breast feeding. High perinatal transmission rate in developing countries is largely due to prolonged breast feeding being practiced more commonly than in developed world. A systematic review of studies done by Dunn [19]et al in 1992 found that the additional risk of transmission through breast milk (over and above the risks of

transmission in-utero and intrapartum) was 14% when the mother had been infected prenatally and 29 % when the mother acquired HIV virus postnatally.

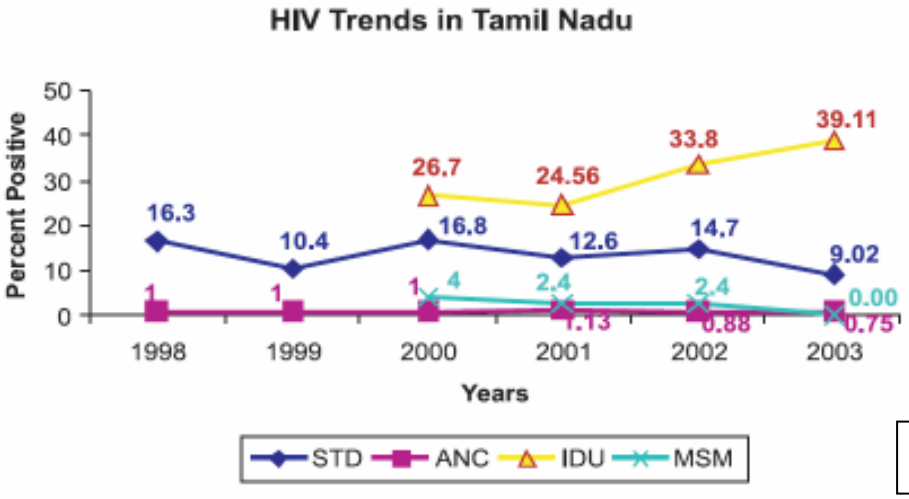
3.1.4 Impact of the HIV epidemic in India

The official Indian figures do not reveal the true picture, presumably for political reasons. There may be many reasons for such ambiguity such as under-reporting due to weaknesses in the surveillance system, bias in targeting groups for testing, and the lack of availability of testing services in several parts of the country. In the context of India's large population, even relatively low rates may actually imply a huge number of people: for example, prevalence of 0.5% means half a million people. The officially declared HIV prevalence rate in India is low (0.7%),[5] which corresponds to an estimated 2 million to 3 million people living with HIV in the country.[20] In state of Maharashtra, HIV prevalence is 60% among sex workers in Mumbai (Bombay), 14-16% in sentinel STD clinics, and over 2% among women attending anti-natal clinics. The prevalence is 6.5% in Namakkal in Tamil Nadu and 5.3% in Churachandpur in the north-eastern state of Manipur.[21]

The Minister of Health, Government of India had reported to the Indian Parliament that there 70,000 HIV infected children currently in the country and nearly 21,000 new infections every year. The National AIDS control Organisation (NACO), supported by UNAIDS and WHO estimates that there are around 2 million to 3.1 million people living with HIV in the country.[20]

3.1.5 Impact of the HIV epidemic in Tamil Nadu

According to the Tamil Nadu Aids Control Society (TNSACS) the total population of Tamil Nadu for the year 2002 was 558.59 lakhs, of which a total of 22,826 cases of AIDS have been reported up to October 2002.



Source: NACO[5]

Tamil Nadu was among the high prevalence states with the prevalence among ante natal women being around 1.13 percent in 2001 which has dropped to 0.5 percent in the 2006. An estimated 11.5 lakh deliveries take place in the state annually; with 55 per cent handled by the state- run hospitals. Around five percent occur at homes under the supervision of midwives and the rest in the private sector.(27) With a prevalence of around 0.5 per cent there would be close to 5,500 deliveries occurring to seropositive women annually. In the absence of any intervention, vertical transmission would lead to 1650 new cases of HIV positive children**.** (22) 20 per cent of these children will die before their first birthday or would develop AIDS.(23)

3.1.7 The diagnosis of HIV infection in children.

The presence of maternal antibodies in the infants blood can persist up to 18months.[24] Hence the antibody tests would be not very reliable as a diagnostic tool. The time taken for the elimination of HIV HIV-positive mother's maternal antibodies from an infant's system (sero-reversion) varies. The majority of uninfected non-breast-fed children will sero-revert by 15 months, but a smaller percentage (1%-18%) will not revert until 18 months.[25] Despite these limitations, HIV ELISA and rapid tests are the most widely available tests, and do provide evidence of exposure.[26] The other means of diagnosis is through virological tests like HIV Immune Complex Dissociated p24 Antigen Assays, HIV DNA PCR, HIV RNA Assays or HIV Peripheral Blood Mononuclear Viral Culture which are very expensive and are usually not available in a resource poor setting.[24]

Pediatric Virology Committee of the AIDS Clinical Trials Group in the United States has proposed definitions for determining in utero versus intrapartum transmission. It is considered that a child with a positive PCR within 48 hours of birth has been infected in-utero. A child who is PCR negative at 48 hours but positive 7-90 days after delivery would be considered to have an intrapartum infection. Two Positive PCR 4 wks apart confirms HIV positivity in an infant.

3.1.6 The Government Response

Although the Government of India has designed various programs to help prevent further spread of HIV, lack of funding and poor regulatory systems are barriers to their implementation. Poverty, illiteracy, gender inequality, and terrorism, all compete with AIDS for scarce resources. Recognizing the seriousness of the situation, the central government constituted a high-powered committee under

the Ministry of Health and Welfare, and subsequently, a National AIDS Control Program was launched in 1987.

The National AIDS Control Organization (NACO) was established in 1992. NACO carries out India's national AIDS program, which includes the formulation of policy, prevention and control programs. In the same year, the government launched a five - year strategic plan for HIV/AIDS prevention under the national AIDS control project. The project established the administrative and technical basis for program management and set up state AIDS bodies in 25 states and 7 union territories. The project made a number of important improvements in HIV prevention such as improving blood safety. To strengthen surveillance the government had established 140 centers and 180 sentinel sites across the country, to monitor HIV trends and the geographical spread of HIV among the general population and at-risk groups, which has now been increased 400 sentinel centers in 2007.[(26)]

Categorization of States

NACO has categorized the states and union territories broadly into three groups depending on the prevalence among the adult population.

Group I – HIGH PREVALENCE STATES: prevalence greater than 5% or more in high risk groups and antenatal prevalence greater or equal to 1%. Maharashtra, Andhra Pradesh, Karnataka, Manipur and Nagaland are included in Group I.

Group II- MODERATE PREVALENCE STATES: prevalence of has crossed 5% in the high risk groups but the antenatal prevalence is less than 1%. This includes states like Gujarat, Tamil Nadu, Goa and Pondicherry.

Group III- LOW PREVALENCE STATES: prevalence is less than 5% in the high risk groups and less than 1% among antenatal women.

3.2. Prevention of parent to child transmission of HIV

The options for preventing vertical transmission were limited in the early stages of the epidemic. Termination of pregnancy was probably the only solution to prevent vertical transmission seen by many. Although this option has not lost its relevance even today, social pressures and longing for motherhood would make most HIV positive mothers opt to continue pregnancy. To prevent the transmission of HIV from mother to child WHO/UNAIDS/UNICEF have developed guidelines also known as the MTCT guidelines. The parent have equal share in the transmission of the infection and not just the mother hence it was changed to Parent to Child Transmission also known as PPTCT.

3.2.1 Components of Prevention of Parent to Child transmission of HIV[27]

The components of PPTCT are Voluntary, confidential counseling and testing (VCTC) services, optimal obstetrical practices, short-course antiretroviral (ARV) therapy for HIV-infected pregnant women, counseling and support about safe infant feeding practices, ARV for the baby at birth and family planning counseling and services that are linked to VCTC.

The best means to prevent vertical transmission is to prevent women getting infected by HIV. Antenatal voluntary counseling and HIV testing (VCT), followed by the provision of short-course Nevirapine prophylaxis is the key intervention advocated in the prevention of vertical transmission of HIV.[28, 29]

3.2.2 Antiretroviral drugs for the mother

Antiretroviral medications reduce vertical transmission by reducing maternal viral load and thereby decreasing viral exposure to the fetus. ART can reduce vertical transmission to around one third as seen in ACTG 076 Trial and the other trials in South Africa and Thailand.[30-33]. In resource poor situation, where patients usually face the problems of non-availability of a specialist, drug resistance, and drug toxicity; mono therapy with Zidovudine (AZT) is the mainstay of antiretroviral therapy in pregnancy. Conventionally, Zidovudine is prescribed in the dose of 100 mg five times a day antenatally and 2 mg / kg as a loading dose followed by 1 mg/kg/hour during labor. Nevirapine in the peripartum period has also been offered as a sole intervention for preventing transmission under the NACO program.

3.2.3 Optimizing the obstetric practices to decrease the viral exposure at birth:

In the early stages of the epidemic the options for preventing vertical transmission were limited. Termination of pregnancy was probably the only solution to prevent vertical transmission seen by many. Although this option has not lost its relevance even today, social pressures and longing for motherhood would make most HIV positive mothers opt to continue pregnancy. The International Guidelines on HIV/AIDS issued by UNAIDS and the OHCHR mandate that "women should be

provided with accurate information about the risk of perinatal transmission to support them in making voluntary, informed choices about reproduction."[34]

3.2.3.1 Elective Caesarean section

The onset of labor brings about changes in the blood flow around the placenta and there may be higher chance of the maternal and fetal blood mixing. Rupture of membranes and exposure to secretion and blood in the birth canal would lead to higher chance of infection. Elective cesarean section (CS) at 38 weeks of pregnancy before the onset of labor or rupture of membrane is said to decreases transmission by 50%-80%.[35] When compared with other modes of delivery Caesarean section has a significant reduction in vertical HIV transmission.[36] The benefits that CS offers mothers who have undetected viral load or receiving HAART (Highly Activated Anti-Retroviral Therapy) is still debatable. Rate of transmission is reduced to 2% when elective CS is combined with AZT prophylaxis. [16]

3.2.3.2 Vaginal delivery:

In 1999 a European- study has found a significant lower rate of vertical transmission with elective caesarean section (1.8%) than those randomized to vaginal delivery (10.5%), but the decrease in transmission risk was not statistically significant among women receiving AZT prophylaxis.[35] In Bombay, Ira Shah showed that vaginal delivery was as effective as caesarean section for prevention of vertical transmission of HIV when added with antiretroviral therapy and no breast feeding.[37] Some argues that elective LSCS with AZT prophylaxis does not seem to have any additional benefit as compared to vaginal delivery with AZT prophylaxis. In 2003 the Public Health service task force in the USA [38] observed that among women without HIV-1 infection, caesarean section was

associated with increased neonatal morbidity, maternal morbidity and mortality as compared with non-surgical delivery .

Thus, the relative benefit of elective cesarean section with regards to mother-to-child transmission of HIV-1 along with possible risks associated with surgical delivery had to be weighed and the decision for caesarean section should be individualized.

3.2.4 Breast feeding:

There is no doubt is that breast feeding provides various benefits to both the infant and the mother. This includes nutritional completeness, eco-friendly, provision immunity, prevention of infection and improved bonding between the mother and child. Unfortunately breast-milk also contains HIV virus and a study done recently has shown cumulative risk of HIV transmission with increasing duration of BF.[39, 40] The exact mechanism of transmission is not known yet but the transmission risk is high enough to advice cessation. The incidence per month was 0.7% in first 5 months, 0.6% during 6 to 11 months and 0.3% between 12-17 months. [41] WHO recommendation to the developed world is not to breast-feed. In developing countries, where mortality is more due to malnutrition and infection as compared to AIDS itself, the choice of BF can be offered after proper counseling. For a mother who is HIV positive, avoidance of all breast milk can be an option if replacement feeding is "acceptable, feasible, affordable, sustainable, and safe". [42] Otherwise, exclusive breastfeeding is recommended during the first months of life. (4-5 months), and breastfeeding should be discontinued as soon as feasible, taking into account local circumstances, the individual woman's situation and the risks of replacement feeding (including infections other than HIV and malnutrition).[43] A systematic review of studies done by Dunn et al in 1992 [19]found

that the additional risk of transmission through breast was 14% when the mother had been infected prenatally and 29% when the mother acquired HIV virus postnatally.

Mixed feeding is discouraged, as mixed fed children are probably more likely to acquire HIV than exclusively breast-fed children. [40] 'When children born to women living with HIV can be ensured uninterrupted access to nutritionally adequate breast-milk substitutes that are safely prepared and fed to them, they are at less risk of illness and death if they are not breastfed. Artificial feeding substantially increases childhood mortality and morbidity in an environment where infectious diseases and malnutrition are the primary causes of death during infancy,

3.2.4.1 Breast Feeding, Replacement feeds and HIV

Breast feeding is traditionally practiced in India and breast milk is the main source of nutrition for infants during their first years of life. Breast feeding provides additional psychological and child spacing benefits to infants and mothers, and is shown to reduce infant and child morbidity and mortality by protecting children from diarrheal disease, pneumonia and other infections**.**[27] Breast-feeding benefits the family and society by protective effects against ovarian and breast cancers.[2]

Breast feeding is the complete food during the first six months of life and early introduction of top feeds has been shown to increase the age specific malnutrition, with increased incidence of gastrointestinal infection. Promotion of breastfeeding has been ranked as most cost-effective intervention for child survival, and could prevent 13–15% of child deaths in low-income countries. [44] Researchers argue that formula-feeding to prevent HIV transmission can be a "safe and viable

option even in resource poor settings" which depends on the availability of "maternal education, clean water, a supply of formula, and access to health care. "[45]

3.2.5 Anti-retroviral therapy for the baby

The use of antiretrovirals at birth has been shown to reduce vertical transmission. A HIV positive pregnant woman presenting in labor with no history of antiretroviral therapy is given Nevarapine. In the HIVNET 012 trial used Nevirapine, a non-nucleoside reverse transcriptase inhibitor a single dose of 2mg/kg given to the neonates within 72 hours of birth. The efficacy in reducing perinatal transmission was 49% using Nevairpine. One must balance the obvious advantages of being cheaper and simpler as compared to Zidovudine therapy or HAART, against the relatively lower efficacy and the development of a major Nevirapine resistant mutation.

3.3 Childhood mortality and morbidity:

The gains made in eighties in child survival through the GOBI interventions- Growth Monitoring, Oral Rehydration Thereapy, Breast feeding initiative and Immunization are being reversed by the AIDS epidemic [27, 44, 46]

3.3.1 Malnutrition and HIV

Malnutrition and HIV infection are inextricably linked. Improving HIV-infected mothers' nutritional status may help to slow the progression of HIV disease and prolong survival. [27, 44] Research suggests that malnutrition increases the risk of HIV transmission from mothers to babies and the progression of HIV infection. In turn, HIV infection exacerbates malnutrition through its attacks on the immune system and its impact on nutrient intake, absorption and utilization. Malnutrition also

increases fatigue and it decrease physical activity and work productivity of people living with HIV and AIDS (PLWHA). Protein energy malnutrition (PEM) is the most widespread nutritional disease among children in all of the developing countries. Children as well as adults are profoundly affected by the indirect consequences of the AIDS epidemic, even if they themselves are not infected. The burden of illness and eventual death of one or both parents has a deep impact on the social, mental and physical environment. For example, childhood malnutrition is one of the more severe and lasting consequences of parental death, A study in Tanzania,[47] found that stunting among poor children under 5 (unknown HIV status) was substantially higher for orphans (51 %) than for children whose parents were both alive (30%) . Higher rates of stunting among orphans were believed to be due to the effects of vertically transmitted HIV on the immune system, increased exposure to infectious diseases such as tuberculosis m disease related poverty and or grief and psychological depression that interferes with caring practices obtaining food and providing meals.

3.3.2 HIV and morbidity

HIV infection causes damage of the cell mediated immunity and subsequent development of various opportunistic infections. Conditions like malnutrition, tuberculosis and acute respiratory tract infections are more common in HIV infected children than in non HIV infected children. HIV infected children with other infections often respond to locally available antimicrobial treatment, but may require longer courses, hence longer duration of hospitalisation.[48]

3.3.2.1 Gastro-intestinal infection:

Diarrhea ranks as the second most common cause of death in childhood. [49] Young poorly nourished children are more susceptible diarrhea than well nourished children. Among the children exposed to

HIV the number of episodes of serious gastrointestinal infection (diarrhea) were observed to have doubled by three months post breast feed cessation.[50] The number of episodes compared to other top fed children born to non HIV infected mothers was the same only the duration of diarrhea was longer. Although 'diarrhoea' is not a single disease entity and has many different etiologies the diagnosis of the syndrome is based on a common set of signs and symptoms, which include alteration of stool consistency and frequency. The frequency and consistency vary across age groups, cultures and individuals, only the change from the usual/ normal is important. Baquai[51] et al in 1991 used as standard definition for diarrhea as three or more loose stools or at least one loose stool containing blood in 24 hrs. A diarrhea- free day was defined by them to be any day with less than three loose stools or stool with no blood. They considered 48 hours or two days of diarrhea free days to consider a new episode as the most accurate measure for the burden of diarrhea disease in the community.

3.3.2.2 Respiratory infection

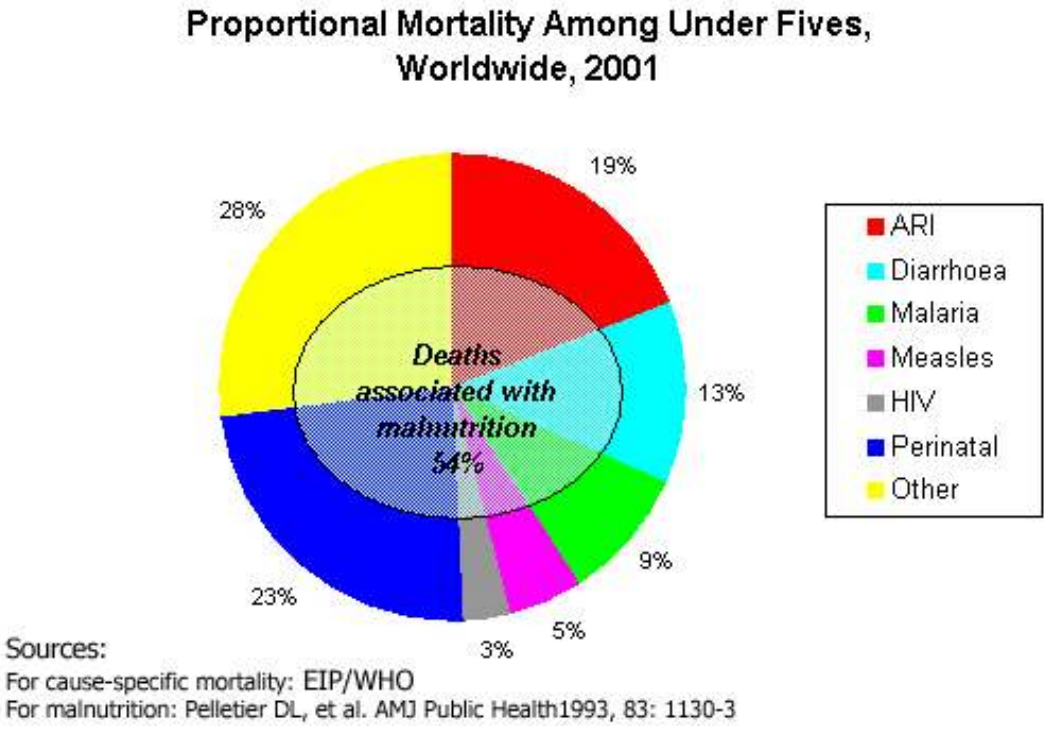
This is the most common cause of death in childhood,[49]and HIV exposed children.[52] Respiratory infections even with no distress can cause reduction of food intake which can push a borderline malnourished child into considerable harm. The child would take a long period of time to make up for this period of poor intake. Respiratory infections usually occur in the cooler months when the population is cloistered indoors with decreased ventilation and close proximity to allow spread by droplet infections.

Symth et al[53] estimated that 11%-45% of the Pediatric pneumonias admitted in hospitals in South Africa were co-infected with HIV. The risk of transmission of tuberculosis from an infected parent

to the child has been well documented. MacNelly et al reported one case of *Pneumocystis jiroveci* Pneumonia (PCP) where a HIV exposed uninfected child got the infection from her mother[54].

3.3.4 Malnutrition and mortality

Malnutrition directly or indirectly contributes to about 54 per cent of the total deaths in developing countries in children under 5 yrs of age as compared to only 5 per cent in developed countries.[26] Severely malnourished children experience substantially higher risk of mortality[55, 56], mortality is said to be 400 times higher in a malnourished child who had measles than in a child of a better nutritional status. HIV contributes only around 3 per cent to the world childhood mortality. Newell et al estimated cumulative mortality rates as 110 per 1000 live births at 12 months and 174 at 24 months among HIV exposed children. Further they say that by 12 months of age, 35 2% of infected children would have died, compared with an estimated 4 9% of uninfected children At 2 years of age, an estimated 52 5% of` infected and 7 6% of uninfected children would have died. [57]



3.3.5 AIDS orphans

Even in countries with mature HIV epidemics, most children (near to 80%) born to HIV-infected mothers are HIV-negative. These children, living with HIV-infected parents or being orphaned after their parents died from HIV/AIDS, face many challenges in every day life. The impact of HIV/AIDS on household economies increases children's vulnerability, though no convincing impact data on children's nutritional status and mortality is available. This is probably related to the fact that traditional practices of child fostering and care within extended families seem to be absorbing the increase in children affected by HIV/AIDS and orphans. However other forms of vulnerability are more explicit. The psychological impact of HIV/AIDS on children in low-income countries has been greatly overshadowed by socio-economic considerations and there is a critical lack of research and interventional studies on counseling, emotional and social support for children affected by HIV/AIDS. Observational studies have shown that orphans were less likely to be enrolled in school than non-orphans of the same age, due to poverty, to the priority given to core family children and to stigmatization. [58] Children are most vulnerable after the death of the mother. It was seen that the death of a mother there would be the death of the child within two years.[47]

The Center for Disease Control (CDC 1999) estimates that one in every three children orphaned by HIV/AIDS is under five and that by 2010, in thirty four countries currently hardest hit by the epidemic, nearly fifteen million children under five will be orphaned by AIDS and many more will be living with sick parents and exhausted caregivers in impoverished conditions. India has the largest number of AIDS orphans of any country in the world, standing at 1.2 million in 2001, and predicted to rise to two million in five years and 2.7 million in ten years.[59]

3.3.6 Cost of illness

The total annual cost of HIV includes the loss of productivity among HIV patients due to sickness and death, the productivity loss of caregivers of AIDS patients, and the cost of management of AIDS patients.

The study by Anand et al. estimated that the annual costs of HIV/AIDS ranges between 0.1 and 1.1 percent of GDP depending on the assumption made about the prevalence rate. The loss of productivity due to premature death and AIDS affected children from birth to eight (those infected with HIV; affected by HIV/AIDS through infection or the illness/loss of one or both parents and/or family members; orphaned due to AIDS; or made vulnerable by the AIDS pandemic) face threats to normal human development beyond those of physical survival. The deprivation of consistent, responsive care and interpersonal and environmental stimulation in children's critical early years of life leads to measurable increases in malnutrition, morbidity, and mortality; this neglect also inhibits healthy psychosocial and cognitive development. Over the long-term, deficient psychosocial and cognitive development among AIDS affected children will have very real significance for the societies in which they live.

In Africa untreated 60% of the children would of HIV before their fifth birth day[60]. The recent advances in anti-retrovirals have prolonged the life expectancy of patients infected by HIV. Earlier the median survival for HIV infected child was 9.2 year now with ART it is 22.4 years.[61, 62] In one study in southern India the median survival was 92 months after seroconversion[63, 64]. The quality of life during this time is the issue. As HIV infected children have the same number of infectious episodes per month but the recovery time is longer, the cost of treatment would be higher.

Schackman et al [62] in November 2006 in study published in Medical Care, estimated that in adults 68% of lifetime HIV care costs are for antiretroviral drugs, 16% for outpatient care, 11% for inpatient care, and 5% for other medications and laboratory costs. This worked out to a cost of USD 2,100 per month (on an average), with a total cost of life time cost USD 618,900.00. Children have higher rates of morbidity and would require more hospitalizations compared to adults. Havens et al in 1996[65] calculated that a life time hospitalization cost of a HIV infected child was $347.656, Hsia et al [66] in 1985 estimated that 83% of the life time cost of care for a HIV Infected child was due to hospitalization cost. Therefore the mean total lifetime cost would be $4118, 863 for a HIV infected Child. The cost of care of a HIV infected child expensive. The burden of Pediatric HIV can be reduced by PPTCT interventions thereby reducing the burden on the already taxed health system along with the cost of caring for a HIV infected child.

3. METHODOLOGY

4.1 Study Design:

This was an evaluation of an uncontrolled intervention group of antenatal women infected with HIV who were under the PPTCT program. The rate of HIV detected among pregnant women, the compliance to PPTCT protocols and the rate of vertical transmission of HIV infection was also calculated. A cross-sectional study was also done to compare the nutritional status of children born to HIV infected mothers with children born to mothers uninfected with HIV from a similar locality and background.

4.2 Study setting:

The Department of Community Health, Christian Medical College, Vellore, India, has been working in Kaniyambadi Block ('service area') for the past 50 years. This region is in the southern state of Tamil Nadu and is a geographically defined area of 127.4 sq. km with an estimated population of 108,800. The community health program operates in all 82 villages in the block. The predominant occupation is agricultural labour while some are marginal farmers. A significant number of young men are in Indian army. A few men and women go to other places for construction work and other jobs.

The Community Health and Development (CHAD) Program is run by the Department of Community Health. Along with the government health services, it provides primary health care including maternal and child health services for the block by a community health volunteer in every village, a health-aide for every 4,500 – 5000 population, a public health nurse for every 5- 6 health-aides and a

medical doctor for every 30,000 population. A mobile clinic offering preventive and curative services visits each village every month. Patients who cannot be treated are referred to the base hospital which offers secondary care services. If tertiary care is needed, patients are further referred to the Christian Medical College and Hospital, where specialty care and advanced laboratory services are available.

The health information system of CHAD program consists of 4-tier monitoring system. The block has been divided into regions with specific personnel in charge of the health of the different regions. The system involves the community health worker, the health aide, the community nurse and the doctor. Every week the community health worker reports to the health aide about pregnancies, deliveries, births, deaths, morbidity, marriages, immunisation, and couples eligible for contraception in the village. This information is verified by the nurse and subsequently by the doctor. Data obtained by the health information system is computerized and linked to every individual living in the block through a unique identification number. The data for the whole block is collated and reviewed each month by the entire health team consisting of the health aides, community health nurses, doctors and other development staff. The information on all pregnant women in this block since 1986 is available in the database. At registration (first visit to CHAD's MCH clinic) at the village, the antenatal women are given a antenatal card. The details on obstetric history, date of last menstrual period, date of last delivery, age, maternal height, high risk factors are obtained and are later entered and updated in the Health Management Information Systems (HMIS) data base. Over 90% of antenatal women in Kaniyambadi deliver in the hospital.

CHAD hospital runs antenatal clinics, well baby clinics, and outpatient and inpatient services for the people from Vellore and surrounding areas ('non-service area'). At the antenatal clinics, group teaching on various diseases, importance of nutrition, rest and warning signals during antenatal period and the need for testing blood for haematocrit, HBsAG and HIV is given. Blood for hematocrit, HIV and HBsAg is collected and tested at the base hospital of CHAD program. Rapid screening tests are done for HIV and HBsAg on the sample. If a sample is positive the sample is retested. If both the tests are positive, the patient and her husband are called to the base hospital maintaining confidentiality and privacy in all aspects. A detailed pre-test counseling is given to the couple and blood is drawn for repeat rapid test and Western Blot. If the repeat rapid test is positive, the sample is sent to Christian Medical College and Hospital Vellore, Department of Virology for ELISA and confirmatory Western Blot. . The couple then receives individual post test counseling. The patient is then required to come to the base hospital high risk antenatal clinic for her monthly antenatal check-up The couples are counseled and various options in terms of mode of delivery and breast feeding are given. Once the patient decides to undergo an elective caesarean section, the patient is referred to the Obstetrics Department at Christian Medical College at 33 weeks. Anti retroviral therapy (Zidovidine) is given for four weeks stating at 34 weeks and elective LSCS is done at 38 weeks, well before the onset of labor. The baby is thereafter given Zidovidine oral suspension for 6 weeks.

4.3 Study subjects:

All women enrolled in the Antenatal program of CHAD – both at the peripheral clinic and base hospital and tested positive for HIV infection and children born to them were included in the study.

30 children born to HIV uninfected women were selected after matching for age and socioeconomic and living conditions whenever possible as a comparison group for the study of growth and nutrition.

4.4 Sample size:

In calculating the sample size we assumed that the vertical transmission in the intervention group would be less than 10 percent as compared to the expected frequency of 30% if no intervention is offered

Sample size was calculated by using the formula, $[\ 2\ \bar{p}\ \bar{q}\ (Z_{\alpha}/2+Z_{\beta})^2\ ]/\ (p1-p2)^2$.

p1 is the probability of vertical transmission with out intervention (30%) and p2 is the probability of vertical transmission with intervention (10%).

The desired sample size is 64. If the sample size finally achieved is 32 the power of the study would be just above 50 percent.

4.5 Data collection:

4.5.1 Identification of study participants

The study group was identified from the CHAD data base and their hospital records accessed to get the residential addresses. Letters were sent requesting them to visit the hospital for follow up and to participate in the study if they were willing. Patients were also contacted through telephones if the phone number was available register. The patients who did not return to CHAD and whose address was wrong were visited by a social worker who knew the patient. The investigator visited the houses of the non-respondents and explained the study to the patient and motivated them to participate in it.

4.5.2 Consent

Patients, who responded and arrived at CHAD, were counseled and a written informed consent was obtained from the mothers by the investigator before testing their child's HIV status.

4.5.3 HIV testing of Children

Children above the 18 months of age who had not been tested earlier at CHAD or CMCH were tested by the rapid ELISA method at CHAD. Children whose age was less less than 18 months of age were tested by PCR. Two samples of blood were collected (six weeks apart when the child was off breast feeds) and sent at 8° degree centigrade to CMCH for PCR and viral load. HIV positivity in children was defined as ELISA reactive which was done twice or positive by PCR.

Compliance to PPTCT was assessed by the visits to CMC, antiretroviral medications before delivery, mode of delivery, the absolute avoidance of breast feeding and child's medication for 6 weeks.

4.5.4 Nutritional status and morbidity pattern of children

The children then underwent a detailed clinical examination. Nutritional status was assessed by recording the height and weight of the child. Signs of vitamin deficiency such as night blindness, bitots spots, dermatitis, bleeding gums were probed for by history and examination. The peripheral blood was collected to screen for anemia. Details regarding presence and duration of respiratory tract infection and number of episodes diarroheal disease in the past month were recorded

A Salter Spring balance was used for measuring the weight of each child less one year old. An electronic weighing machine in the OPD was used to weight the older children. A height rod was used to measure the height of each child in the OPD. If there were children who wouldn't come to CHAD, a height rod was used or if situations so demanded a metallic measuring tape was used to make markings on a wall and the child's height was measured against this. Weight was taken on the Salter or Electronic balance and was noted to the nearest 100 grams. Height was measured for children above 2 yrs and the length for children up to 24 months. This was measured by making the child to stand erect against the wall or the height rod, with both his/her feed together and face set straight. The marker or a flat board was kept on top of the child's head and the corresponding reading of the height on the wall was noted to the nearest millimeter using a metallic tape.

4.5.5 Non-respondents:

In case of non respondents or letters returning due to death, wrong address or patient having migrated without leaving a forwarding address, the patient records were checked for details of the date or diagnosis, date of delivery. Records of the children were also checked for results of the HIV testing.

4.6 Analysis:

The raw data was entered into Epidata. Data with nutritional anthropometry was entered and analyzed using Epi Info 2002- Nutstat. The dietary caloric and protein contents were calculated used the NIH Scale. The data was analysed using Nutstat Epi-Info 2002 and SPSS for Windows 12.0 software.

5. RESULTS

5.1 Screening for HIV

Two groups of antenatal women were tested; those from Kaniyambadi block (field based screening as a part of the primary heath care service offered to the block, also referred to as the service area) and hospital based screening to all non-Kaniyambadi users of CHAD hospital's services (referred to as non-service area). The screening for HIV infection and presence of surface antigen for Hepatitis B infection (HBsAg) among the antenatal women in Kaniyambadi block began in May 2002 and is on-going. From May 2002 to December 2006 there were 10,616 pregnancies in Kaniyambadi block and 95.36 percent (10123) of them received antenatal care from CHAD services. Of all women who were registered for antenatal care, 91 women (0.9%) were not tested as they delivered before the test could be done. Only one woman refused to undergo screening for HIV. Hence, the overall rate of screening for HIV among those who received antenatal care from CHAD service was 99.9 percent. Of all pregnancies in this block 94.5 percent were screened for HIV.

5.2 Prevalence of HIV infection among antenatal women in Kaniyambadi block

The annual prevalence of HIV infection among antenatal women in Kaniyambadi ranged from 0.6 % in 2002 to 0.24% in 2006 and the overall prevalence was 0.298% (95% CI 0.192-0.406) as shown in Table1. A total of 28 antenatal women with HIV infection were identified during this period in Kaniyambadi block and two women who were positive became pregnant twice. A gradual reduction in the prevalence was seen over the years (**Chi Square for trend** value= 4.902 and p-value= 0.0268) which was statistically significant.

Table 1: HIV prevalence in Kaniyambadi among antenatal women (May 2002- Dec 2006)

Year	No. tested	No. Positive	Prevalence %	95%CI	
				Lower	Upper
2002	1514	9	0.591	0.207	0.982
2003	2089	7	0.334	0.087	0.583
2004	2252	7	0.310	0.081	0.541
2005	2094	2	0.095	0.000	0.228
2006	2083	5*	0.239	0.030	0.450
Total	10032	30**	0.298	0.192	0.406

Chi Square for trend value= 4.90, p-value= 0.027
* 2 HIV positive got pregnant the second time ** 28 women and 30 pregnancies

5.3 Prevalence of HIV infection among antenatal women attending CHAD hospital:

While women from Kaniyambadi block receive antenatal care from the peripheral program, the base hospital of Community Health Department of Christian Medical College Vellore provides antenatal care to women belonging to nearby areas. The screening service was extended to the CHAD hospital only in 2004. A total of 6081 women were registered for antenatal care in CHAD from April 2004 to December 2006. The prevalence of HIV infection among them ranged from 0.37 in 2004 to around 0.23 in 2005 with an average annual prevalence over the last three years being 0.3 per cent and no change in the prevalence was noticed during thee years (**Chi square for trend** value = 0.075 and p-value = 0.7849).

As shown in Table 2, total of 6080 women were screened for HIV infection 18 HIV women were identified as infected with HIV.

Table 2: HIV prevalence among antenatal women attending CHAD hospital antenatal program (April 2004- Dec 2006)

Year	No. tested	No. Positive	Prevalence %	95%CI	
				Lower	Upper
2004	1623	6	0.369	0.074	0.665
2005	2186	5	0.229	0.028	0.429
2006	2271	7	0.308	0.080	0.536
Total	6080	18	0.296	0.159	0.433

Chi Square for trend value =0.075, p-value = 0.7849

5.4 Description and outcome of pregnancies in Kaniyambadi block (May 2006-December 2006):

There were 10619 antenatal women in Kaniyambadi block during the period of May 2002 and December 2006, details of 9849 are available with the CHAD database and this has been used for analysis. The HIV prevalence among the antenatal women who were temporary residents was 0.4 per cent and 0.3 per cent among permanent residents (prevalence ratio [PR] 1.335 and 95% CI 0.63-2.801). Among the HIV infected women, 46.7% (14 women) were primigravida where as 43% of the uninfected women were primigravidae, There were 51 antenatal women who had more than 5 pregnancies and one of them was HIV positive. The overall prevalence among primigravida and multigravida were similar (0.3%) and the prevalence ratio (PR) was 1.16 (0.566, 2.327).

The prevalence of HIV infection among women according to parity, number of living children and number of abortions were similar (table 3).

Table 3: Comparison of HIV infected and uninfected antenatal in Kaniyambadi by their residential status and obstetric scores

	HIV infected (n=30)		HIV un-infected (n=9813)		Prevalence ratio (95%CI)
	No.	%	No.	%	
Residence					
Temporary (n=2878)	11	0.4	2967	99.6	
Permanent (n=6867)	19	0.3	6848	99.7	1.335 (0.636- 2.801)
Gravida					
1st (n= 4234)	14	0.3	4220	99.7	
2nd or more (n=5615)	16	0.3	5599	99.7	1.16 (0.566, 2.327)
Parity*					
1 (n=3727)	11	0.3	3716	99.7	
2 or more (n=1515)	4	0.3	1511	99.7	1.12 (0.357, 3.505)
No of Living					
0 (n=4802)	15	0.3	4787	99.7	
1 or more (n=5097)	15	0.3	5082	99.7	1.050 (0514, 2.14)
Abortion					
0 (n=8759)	27	0.3	8732	99.7	
1 or more (n=1084)	3	0.3	1081	99.7	1.114 (0.338, 3.665)

* Nulliparous (primigravida and previous abortions) were not included

64.5 per cent of women from Kaniyambadi block delivered in CHAD. During the period May 2002 to December 2006, three HIV infected women delivered vaginally in CHAD. The main referral center for CHAD was the Obstetric department of CMC Hospital (CMCH). Only 5.7 per cent of all births in Kaniyambadi were in CMCH while 72.4 per cent of the HIV infected women delivered in CMCH. Home deliveries accounted 10.76 per cent (1047cases) of the deliveries. Of the home

deliveries, 2.29 percent (24 cases) were conducted by untrained birth attendants, including one HIV positive delivery. Caesarian Section was the mode of delivery for 69 per cent (20 cases) of HIV exposed children and for 10.3 per cent (999 cases) unexposed children during May 2002 to December 2006. There were over 83.55 per cent normal delivery among the uninfected and 30.00 per cent (9) among the HIV infected women. The sex ratio among the children at birth for period May 2002 to December 2006 was 933 among the infected and 924 among the uninfected.

Table 4: Details of delivery among HIV infected and uninfected antenatal women in Kaniyambadi

	HIV infected (n=29)		HIV un infected (n=9687)		Total (9716)	
	No.	%	No.	%	No.	%
Place of delivery						
CHAD	3	10.30	6265	64.8	6268	64.5
CMC	21	72.45	534	5.5	555	5.7
OTHER HOSP	4	13.79	1843	19.03	1847	19.01
HOME	1	3.45	1045	10.7	1046	10.8
Mode of Delivery						
Vaginal Delivery	9	31.0	8295	85.6	8308	85.46
LSCS	20	69.0	997	10.3	1019	10.48
Instrumental	0	0	395	4.1	395	4.06
Baby's Condition at birth						
STILL BORN AND END	1	3.4	299	3.1	300	3.1
SICK	1	3.4	238	2.5	239	2.4
HEALTHY	27	93.2	9150	94.4	9177	94.6
Sex of the baby						
Female	14	48.3	4653	48.0	4667	48.0
Male	15	51.7	5033	52.0	5048	52.0

The perinatal mortality rate was 31 per 1000 births among uninfected and 34 per 1000 births in infected group. The mean maternal age of the HIV exposed children was 24 years with SD of 3.5 and 22.95 years with a SD of 3.59 among the uninfected, with a p-value of 0.104.

The mean birth weight of children born to HIV infected mothers in Kaniyambadi was 2.524 kg with a SD of 0.67 (95% CI 2.274-2.774) and that of the uninfected mothers was 2.794 kg with an SD of 0.52 (95% CI 2.783- 2.805). The difference in mean birth weight among children born to infected and uninfected mothers was statistically significantly (p-value 0.007).

5.5. The outcome of pregnancies with maternal HIV infection:

A total of 48 pregnancies with HIV infection (30 from Kaniyambadi and 18 from CHAD hospital) were thus identified. There were 46 women who were infected and two women had 2 pregnancies during this period. Two women preferred to under go medical termination of pregnancy, one woman had a missed abortion and six were lost to follow up during the antenatal period.

Five of those lost to follow up were from non-service areas and could not be traced; one was from service area but moved to her parent's house due to her husband's death and could not be followed up. Two women were yet to deliver at the start of the study. Of the 39 deliveries, 10 (25.6%) delivered vaginally and 29 (74.4%) delivered by elective caesarian section at 38 weeks. The reasons for vaginal delivery were varied and are listed in Table 5.

Unwillingness for Caesarian section was cited as the reason for vaginal delivery, while late registration/ or contact of the patient was the reason for 20 percent. Of the four who were not willing

for Caesarian section, two were unwilling to accept their HIV status and one woman went on to have two pregnancies after the HIV status was known but she did not want any surgical procedure on her.

Table 5: Reasons for vaginal delivery

Reasons	No. (%)
Intrauterine death of fetus	1 (10%)
Preterm labour	1(10%)
Mother – sick	1(10%)
Moved out	1 (10%)
Late registration	2 (20%)
Unwillingness to undergo Caesarian section	4 (40%)
Total	10

Of the 39 deliveries with maternal HIV infection, one resulted in a still birth and one neonate died due to prematurity. Two children died before the age of one year due to acute gastroenteritis. One refused to have her child tested but was observed to be healthy. A total of 32 children were tested for HIV infection.

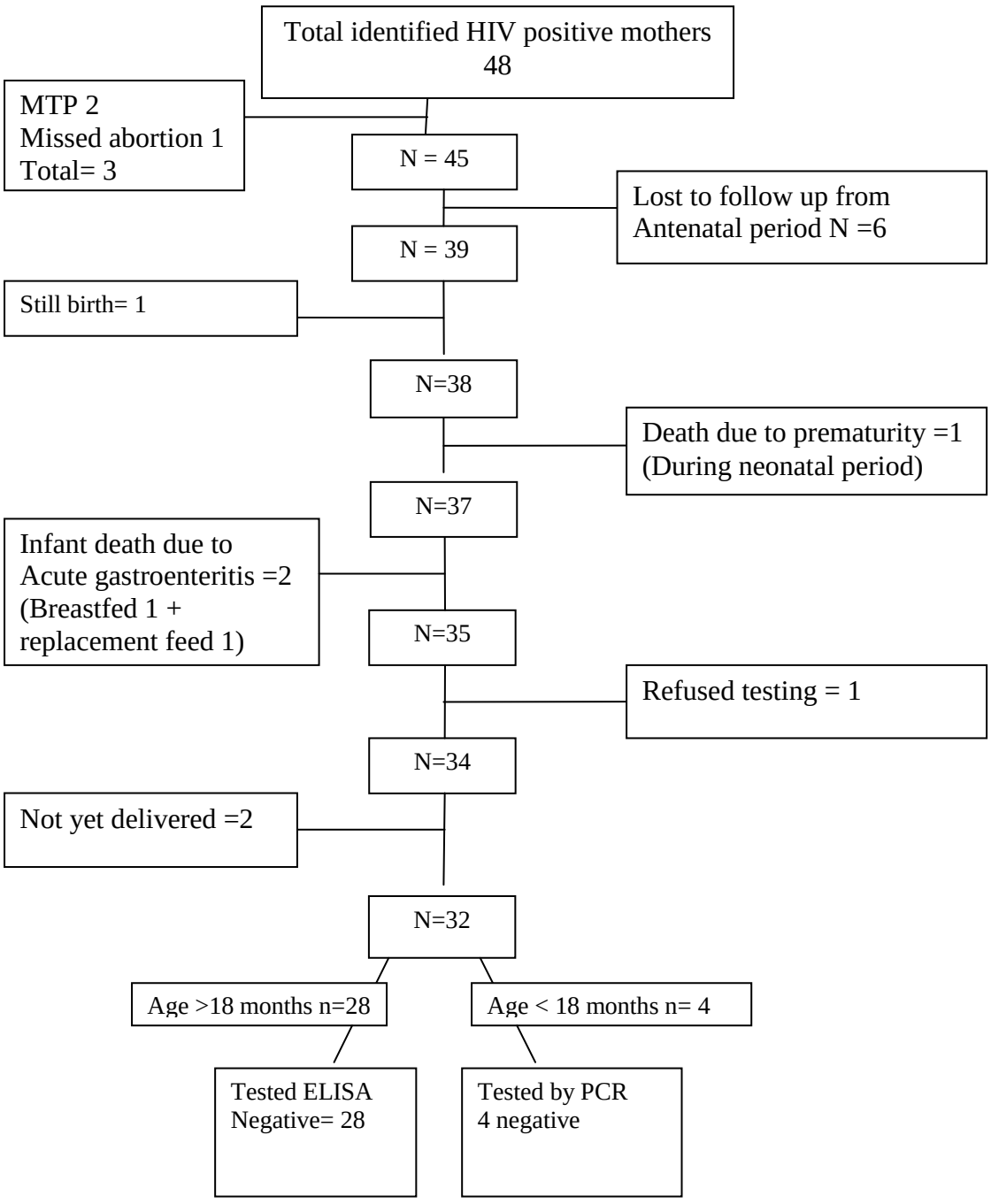
5.6 Infant mortality among children born to HIV infected mothers:

The infant mortality rate in this group was 79 per 1000 live birth (3/38). Two infants died due to gastrointestinal infections. One infant born by Caesarian section and formula fed, succumbed to diarrhea at the age of one month. The second infant born by vaginal delivery (as the mother was sick), was exclusively breast fed, developed protein energy malnutrition (failure to thrive) had acute gastrointestinal infection and died at 6 months of age. One child with severe intra-uterine growth

retardation and a preterm birth, died in the first month. One child who was tested negative at the age 15 months died at 18 months due to acute gastroenteritis.

5.7 HIV status of children born to mothers infected with HIV:

Flowchart 1: Outcome of pregnancies of HIV positive women.



HIV testing is usually done by ELISA after 12 months of age to confirm diagnosis of HIV infection among children born to HIV infected mothers**.** ELISA testing was done for 28 children and four less than 12 months had their status checked by Polymerase Chain Reaction Test (PCR) to confirm the presence or absence of the HIV virus in their blood. All 32 children were found to be negative for HIV infection. The vertical transmission rate therefore among the tested was zero. Flowchart 1 shows the details of pregnancies with HIV infection.

5.8 Compliance to PPTCT protocols

Pretest written and oral consent were taken from all women. Confirmatory tests (Western Blot) and post counseling were done to 98 per cent of women that were identified as positive by ELISA test for HIV. One woman (2 per cent) was not given post test counseling as the patient went away for delivery immediately after the test was given. The patients and their husband's were counseled on multiple occasions during the antenatal period. 97.92 per cent of the partners of the HIV positive antenatal women were counseled and tested. Five of the husbands were tested as negative (10.4 % partner discordance). One couple separated before the diagnosis and her spouse who was living in another state refused to come for counseling.

The compliance to the PPTCT protocols by the HIV positive mothers of children that were tested is shown in the Table 6. Antiretroviral therapy from 34 weeks of gestation onwards was taken by 90.6 per cent of women. Pre-labor Caesarian section at 38 weeks was possible in 84.4 per cent of the cases.

Majority of children (78.1 per cent) born to HIV infected mothers were not breastfed by their mothers. Four children were exclusive breastfed and 3 received mixed feeds). There was one patient

whose uninfected relative “wet nursed” the infant till the age of three months (considered as avoided mother’s breast milk). All 32 babies received ART within 72 hours of birth irrespective of the place of delivery.

Table 6: Compliance to the PPTCT protocols by HIV positive mothers of children tested

	YES	NO	Total
ART at 34 weeks	29 (90.6%)	3 (9.4%)	32
Elective Caesarean section	27 (84.4%)	5 (15.6%)	32
Avoidance of Breast Feeds	25 (78.1 %)	7 (21.9%)	32
ART to baby for 6 wks	39 (100.0%)	0 (0.0%)	32

5.9 Morbidity and nutritional status of children born to HIV infected mothers:

The morbidity and the nutritional status of children born to HIV infected mothers were studied at the time of their follow up. A total of 28 children born to HIV infected mothers and 34 children born to

Table 7: Socio- Demographic Details of HIV exposed and unexposed children interviewed

	HIV exposed (n=29)			HIV unexposed (n=34)		
	Mean	SD	Median	Mean	SD	Median
Mothers age in years	26.69	3.98	27	24.71	2.64	25
Mothers Education in school years	7.81	4.22	9	7.58	3.05	8
Fathers age in years	32.63	4.40	32	31.11	3.34	30
Fathers Education- in school years	6.83	3.90	8	8.26	4.22	10
Per capita Income in Indian Rupees per month	476.00	287.88	354	474.37	288.46	400

HIV uninfected mothers from similar socioeconomic status were studied. The socio-demographic details of the children and the mother who were interviewed are briefly described in Table 7. The

average age of the mothers was 26.69 years among the exposed and 24.71 years among the unexposed. The mean education of mothers was comparable between the exposed and the unexposed at 7.81 and 7.58 yrs of schooling respectively. The fathers' ages were comparable with the mean age being 32.63 years among the exposed and 31.11 years among the unexposed. The average education of fathers of exposed children was 6.83 yrs of schooling while it was 8.26 yrs of schooling among the unexposed. The per capita income per month was Indian Rs 476.00 for the exposed and Indian Rs. 474.37 among the unexposed.

The occupation of the fathers of HIV exposed and unexposed children are comparable as shown in table 8. They mostly belong to the unskilled and semi- skilled socio economic bracket. The percentage of fathers who were drivers in the two groups were comparable at 14 .3 and 14.7 per cent respectively. There were two fathers who were employed as watchmen among the HIV exposed.

Table 8: Father and mothers occupation of the HIV exposed and unexposed children interviewed.

Fathers occupation	Exposed		Unexposed	
	No.	%	No.	%
unskilled	11	39.3	13	38.2
skilled	4	14.3	4	11.8
transport	4	14.3	5	14.7
mason	4	14.3	4	11.8
others	2	7.8	8	23.6
Mothers occupation	No.	%	No.	%
unskilled	9	32.1	5	14.7
housewife	17	60.7	27	79.4
others	2	7.2	2	5.8

The occupation of mothers of HIV exposed and unexposed children show that there are more unskilled workers among the mothers of HIV exposed children compared to the unexposed. After house wife/ household work, 32 per cent (9 mothers) are employed as unskilled daily wage workers among the exposed while it is only 14.7 per cent among the unexposed. There was a mother who worked as mason among the exposed which was listed as others

5.10 Dietary intake– calories and protein intake of HIV exposed and HIV unexposed children.

Using the 24-hour recall method the protein and calorie intake was calculated. The mean calorie intake was 84.77 per cent of the daily required amount for that age among the children born to HIV positive mothers and 85.04 per cent of the daily required amount for that age unexposed (Table 9). The difference in mean calorie intake was not significant. The intake of protein according to the recommended daily allowance was higher in both groups (Table 9).

Table 9:Comparing the Calorie and Protein intake among exposed and unexposed children

		N	Mean	Std. Deviation	Std. Error Mean	Median
Percentage of required calories per day	Exposed	25	84.77	14.09	2.82	87
	Unexposed	32	85.04	15.91	2.81	84
Percentage of required protein per day	Exposed	25	179.4	67.06	13.69	168.28
	Unexposed	32	160.78	43.77	7.74	157.88

5.11 Nutritional status of children

The height and weight were used as the marker for the growth and of malnutrition in the exposed and unexposed children**.** The nutritional statuses of children who are exposed and unexposed to HIV infection are given in table 10.

Table 10: Nutritional status of children exposed and unexposed to HIV

Malnutrition	HIV exposed n=25	HIV unexposed n=31	χ^2 value and P -value
Gomez criteria			χ^2=2.99, P=0.22 degree of freedom=2 missing data: exposed=1 unexposed=1
Healthy	7 (28.0%)	7 (22.6%	
Grade 1	9 (36.0%)	18 (58.1%)	
Grade 2	9 (36.0%)	6 (19.4%)	
IAP classification			χ^2 =0.11, P = 0.77 degree of freedom=3 missing data: exposed=1 unexposed=1
Normal	15 (60.0%)	17 (54.8%)	
Grade 1	7 (28.0%)	11 (35.5%)	
Grade 2	3 (12.0%)	2 (6.5%)	
Grade 3	0 (0%)	1 (3.2%)	
Weight for height			χ^2 =0.5,1 P=0.47 degree of freedom=2 missing data: exposed= 6 unexposed=4
Normal	9 (50.0%)	17 (60.7%	
Mild wasting	7 (38.9%)	9 (32.1%)	
Moderate wasting	2 (11.1%)	2 (7.1%)	
Height for weight			χ^2=0.02,P= 0.863 degree of freedom=3 missing data: exposed=6 unexposed=4
Normal	8 (44.4%)	13 (46.4%)	
Mild stunting	7 (38.9%)	11 (39.3%)	
Moderate stunting	3 (16.7%)	2 (7.1%)	
Severe stunting	0 (0%)	2 (7.1%)	

Using the Indian Academy of Pediatrics criteria for malnutrition, around 40 percent of HIV exposed children were malnourished while 45.5 per cent of unexposed children had some malnutrition. Table 10 shows that around 40 percent of exposed children had mild-moderate degree of wasting and as compared to 39.9% among the unexposed, while 55.6 per cent of HIV exposed children were stunted and 53.6 per cent of unexposed children were stunted.

The Odds ratio (OR) was calculated to for maternal HIV infection and nutritional status (healthy vs any degree of malnourishment). The OR in the Gomez classification was 1.33 with a p-value of 0.7, and in the IAP classification it was 1.24 with a p-value of 0.7. The weight-for-height OR=0.65 with p-value =0.5 and the height for weight OR=0.80 with a p-value of 0.13.

Children exposed and unexposed to HIV were screened for anemia taking blood for PCV and it was found that 68 per cent of the children had mild anemia (PCV between 30-36%) and 10 per cent of them had moderate anemia as shown in Table 11.

Table 11: Screening for Anemia among the HIV exposed and unexposed children

PCV	HIV exposed (n=20)	HIV unexposed (n=30)	Total (n=50)
Normal > 36	4 (20.0%)	7 (23.3%)	11 (22.0%)
Mild 30-36	14 70.0	20 (66.7%)	34 (68.0%)
Moderate 25 <30	2 (10.0%)	3 (10.0%)	5 (10.0%)

5.12 Morbidity among HIV exposed and unexposed children

A one month recall was used to look at the morbidity pattern of diarrheal and respiratory illness in the last one month among the exposed and unexposed children. The incidence of diarrhea was 33.4 per cent among the exposed in the last month. While among the unexposed it was less than 7 percent.

Table 12 shows the number of respiratory illness that were present in the exposed and the unexposed children in the last one month. Among the HIV exposed children, 61.5 per cent had at least one episode of respiratory infection in one month while in the unexposed it was 73.3 per cent.

Table 12: Morbidity in the last month among HIV exposed and unexposed children

	Exposed	Unexposed
Morbidity in the past month		
Yes	21 (87.5%)	22 (68.8%)
No	3 (12.5%)	10 (31.2%)
Respiratory Tract Infection		
No	10 (38.5%)	8 (25.7%)
Yes	14 (61.5%)	24 (74.3%)
Diarrhea		
No	16 (66.7%)	26 (92.9%)
Yes	8 (33.3%)	2 (7.1%)
Tuberculosis		
Yes	1 (4.2%)	0 (0%)

Among exposed children, 8 (33.3%) had diarrhea during the past one month and 2 children (7.1%) in the unexposed group had diarrhea. One child in the exposed group was on treatment for tuberculosis.

6. Discussion

The study has been done in a rural block in Tamil Nadu, where the health indicators like birth rate, literacy, infant mortality rate, maternal mortality rate and immunisation status are better than the state and national figures and also in some case to that of Kerala.[67] There is a health care delivery system in place reaching every pregnant woman and every under 5 year old child. The setting of this study enables us to study the impact of similar programmes in near-ideal conditions.

6.1 Vertical transmission rate

The vertical transmission rate of HIV without any intervention is around 30 percent in developing countries.[69] Studies in Thailand[30] and South Africa (Kwazulu Natal)[31, 33, 70] showed that the vertical transmission would fall by two third with PPTCT interventions.[32] Hence, one would expect mother to child transmission to fall from 30 percent to 10 percent with PPTCT intervention. In 2001, Merchant[16] et al in Bombay claimed that vertical transmission could be reduced to 5.8 percent with ART before- onset of labour, elective Caesarian Section, ART for the child and total replacement feeds

The current study showed that the vertical transmission rate was 'zero'. Hence, "Zero patient" design was used [71] to compute the upper limit of 95% confidence interval. The calculation is as follows:

The upper limit of 95% CI $= 1- (0.05)^{1/n}$

$= 1- (1+ \text{Log}_e 0.05)/n$

$= 1- (1+ (0.2999)/n)$

$= 3/n$

With the sample size of 32, the upper limit of the 95% CI would be 9.375% (3/32*100).

6.2 Time Trends HIV prevalence of among antenatal women in Kaniyambadi block

The HIV prevalence in India has been a major source of debate. The prevalence of HIV varies from state to state.[5, 26] The prevalence in Tamil Nadu among antenatal women was 1.2% in 2001 but has fallen to 0.6% in 2006.[22] The HIV prevalence in Kaniyambadi block ranged between 0.6 % to 0.1% from May 2002 to December 2006 (Chi-Square for trend value- 0.075 and p value- 0.7849). The prevalence of HIV among antenatal women in Kaniyambadi block has always been less than the state average. The apparent increase in the prevalence in 2006 as compared to 2005 was because of two previously positive women becoming pregnant again.

According to NACO the prevalence of HIV in the state was based upon the data gathered from sentinel sites and was then extrapolated onto the general population. In Tamil Nadu 32 sentinel sites were used by NACO and 8 sentinel sites for antenatal screening showed a prevalence of greater than 1%.[5] There was no community based study on the prevalence of HIV among antenatal women. The current study gives the community based prevalence of HIV of Kaniyambadi block in rural Tamil Nadu as 0.3% (0.192 – 0.406).

The gradual decrease in the number of cases could be explained by the multiple inputs made available in the community such as increased awareness on HIV/AIDS[5] leading to probable behavioral change safe sexual practices, safe blood and injection practices. The state also shows a similar trend.[5, 72]

6.3 Time trends in the HIV prevalence among antenatal women seeking antenatal care at CHAD hospital

In April 2004, HIV screening was extended from Kaniyambadi block to patients coming to CHAD Hospital for antennal care. These were patients from Vellore town, Ussor, Anaicut, Arni and other neighboring blocks and districts. Among those registering in CHAD, a total of 18 patients were detected to be HIV positive with a prevalence of 0.37 percent in 2004 and 0.21 in 2005 and 0.31 in 2006 (Table 2). In a study in 2004 by Lionel J et al,[73] the antenatal prevalence of HIV was 0.5% in obstetric department of CMCH . However, the prevalence of HIV infection in the antenatal clinic has always been lower than the state's overall prevalence and lower than that at CMCH.

6.4 Compliance To PPTCT protocol

The protocols developed to prevent parent to child transmission of HIV have to be adapted according to local settings. In resource poor settings, programmatic issues like availability of ART, the lack of resources for elective caesarian section, the high cost of replacement feeds are determinants of the degree of compliance. In this study, the compliance with pre-delivery ART was 90.6 percent. This is despite the fact that the rural women are reluctant to undergo Caesarian Section due to prolonged hospitalisation and a fear that it affects their well being, the compliance with elective Caesarian section among HIV infected mothers was 84.4 percent.

Breast Feeding is an age old cultural practice in Tamil Nadu. Though an alternate feed (cow's milk, formula feeds etc) is not alien to today's rural population, total avoidance of breast milk is not an accepted practice. Despite the cultural practices and maternal instincts, 78.1% of the women avoided breast feeding their children. In a study in urban Pune,[74] it was shown that only 28.9% babies born

to HIV positive mothers were exclusively artificially fed. Some of the factors that perhaps contribute to the poorer uptake/non-response could be cultural practices in rural South India. Societal pressure to breastfeed the baby could lead to mixed feeding practices. Factors associated with an increased risk for mixed feeding included traditional infant feeding practices, problems during night time, differing advice from hospital staff and the lack for resources to buy replacement feeds.

The WHO recommends that in resource poor countries the benefits of breast feeding outweighs the short term benefits of formula feeds.[39] Kuhn et al [39, 75] estimated that when infant mortality rates are greater than about 40 per 1000 live births, providing formula milk to HIV-infected women would result in the excess number of deaths arising from formula use being the same or greater than the number of HIV infections that might be prevented.

Compliance with ART for the child after birth was 100 per cent. The PPTCT programme could mange to achieve 72 percent compliance to all four requirements of PPTCT protocol. The overall compliance of 71.9% hence represents an overall programme efficiency/acceptability. It appears safe to conclude that when there is a high level of compliance the overall impact will be will bigger

The high compliance to PPTCT protocol was due to the efficient system which is in place. This includes an antenatal care program which is able to reach all women appropriate proper counseling services, an efficient system to follow up the positive mothers, confidentiality and an efficient referral system.

6.5. Screening for HIV

Screening for any disease is not merely to estimate the prevalence but to intervene appropriately, mitigating its otherwise devastating effects. HIV is among the few diseases where screening can

actually reduce disease transmission. The CHAD Health Management Information system shows that 94.5 % of all the pregnancies in Kaniyambadi block were registered with CHAD programme and all except one accepted and underwent testing. In Pune, the acceptance to testing was 82 per cent in the antenatal clinic and 68 per cent in the delivery room.[22] Among women registered for antenatal check up at the community and CHAD hospital, 99.99 percent were screened for HIV (with only one refusal in five years at the community and one in the hospital). Mass education and information campaigns have led to the greater awareness of HIV and acceptance for screening. The 'CDC Guidelines (2007) for antenatal women' require testing of all antenatal women as a routine, with pre test counseling and consent, just as with any other test. Non-acceptance of the test would be provided and an "opt out" would not affect other aspects of health care for the patient. HIV testing experience has hence been largely successful and acceptable to the users.

The extremely high rate of screening and better compliance to PPCTC protocol could be achieved because of the proper functional health care delivery system, regular follow up and social support and good referral system. However, the high cost of the program has public health experts seeking justification for the effort and energy being utilized in preventing vertical transmission and childhood HIV infection.

To justify the decision, a statistic called Numbers Needed to Screen (NNS),[71] a mathematical model, could be used to calculate how many persons have to be screened to prevent one case in the population. The model uses the prevalence with and without intervention. The number needed to treat is calculated from the attributable risk. The number needed to screen,[71] can be calculated using the current prevalence and the number needed to treat (NNT) .

6.6 Numbers Needed to screen (NNS)

Taking the vertical transmission rate of HIV infection without any intervention as 30 percent and after intervention as 10 per cent[16], the absolute risk reduction would be 20. The numbers need to treat to prevent one case of vertical transmission of HIV would be 5. The potential reduction in exposed group not developing infection would be 66.7%. The numbers needed to screen would be NNT divided by the current prevalence of HIV infection (0.3%) which is 1667. In order to prevent one case of vertical transmission, 1667 antenatal women would have to been screened in a programme that provides intervention to all women with HIV infection.

6.7 The cost to attain zero transmission

The cost of preventing one case of vertical transmission in Kaniyambadi would then entail the following direct costs:

Table 13 Cost of Preventing one case of vertical transmission of HIV

	Number	Unit Cost (Indian RS)	Total cost
Number needed to Screen	1667		
Test Kits	1667	100	166,700.00
Numbers needed to treat	4		
OPD Charges for high risk ANC	4 x 6	45	1080.00
Cost of ART from 34 weeks	4	350	1400.00
Elective Caesarian section	4	25000	100,000.00
ART for the baby	4	350	1400.00
Replacement feeds	4 x 6	390	9360.00
Grand Total			**292,540.00**

HIV Test Kits would be required for 1667 women (Rs 1, 66,700) and 5 HIV positives would be identified by those tests. The costs for travel, counseling and re-testing were not included in this calculation. The four positive women would have to come to the hospital for monthly antenatal visits in the high risk antenatal OPD (Rs 1,080). They would be started on ART from the 34 week for one month (Rs.1, 400). The cost of their elective Caesarian section in a tertiary care center would be Rs 100,000 (Rs 25,000 per person). After birth, the babies would receive ART for 6 weeks (Rs. 1,400) and replacement feeds for 6 months (Rs.9, 360). To prevent one case of vertical transmission, we would have to screen 1333 antenatal women and treat 4 women and their babies, at a cost of Rs. 2,92,540.00 (USD 7313.00 at the rate of 1 USD= Indian Rupees 40.00)

In comparison, to prevent one case of Rh-Hemolytic Disease of the newborn (HDN), Joseph [76] estimated that with the current prevalence of Rh negative population of 5% and the average family size of 2.3, the incidence of Rh-Hemolytic Disease of the newborn would be 5.98 per 1000 live births without intervention and 0.28 per 1000 live births with intervention. The number needed to treat (NNT) to prevent one case of any form of the disease would be 175 women with Rh negative phenotype. To identify 175 Rh negative women 3,509 antenatal women would have to be screened (Rs 491,260.00). To check for any isoimmunisation an indirect Coombs (ICT) would have to be done (28,875.00) on all RH negative mothers. At birth the babies blood group would be tested (Rs 24,500.00). Considering the probability of husband being RH negative or RH positive with heterozygous genotype, 60% percent babies (107) would be Rh positive and would have to be tested for hemolysis by direct Coombs test (Rs.17,655.00) and 107 mothers with positive babies would be administered injection Anti-D at a unit cost or Rs 2700.00 (Rs.2,88,900.00).

Table 14 Cost of preventing one case of Rh-HDN

	number	Unit cost	Total cost
Cost of screening	3509	140	491,260.00
Number needed to treat	175		
Coombs test Indirect	175	165	28875.00
Baby's blood group	175	140	24500.00
Coombs test direct	107	165	17655.00
Injection Anti-D	107	2700	288,900.00
Grand Total			**851,190.00**

To prevent one case of Rh HDN, Rs 851,190.00 (USD 21,279) would be spent. This cost is three times the cost of preventing one case of vertical transmission of HIV.

In the light of competing causes for childhood morbidity and mortality the cost effectiveness of preventing one vertical of transmission of HIV and preventing one case of Rh-HDN have to be considered.

6.8 Cost of HIV prevention and treatment

The HIV pandemic has a major impact on the economic development of the country and the region. Various studies have attempted to calculate the cost of treatment and care of Pediatric HIV. NACO in a recent press release reported that cost of ART alone was Rs.8000 per person per year.[77]

In developed countries, without treatment the median life span of a child affected by Vertical Transmission is 9.2 yrs.[61] And in developing countries, nearly 60% of HIV infected children die before their fifth birthday. With the better availability of anti-retrovirals it is now estimated that the average life expectancy of HIV infected children has moved up to 22.4 years.[62] Children with HIV infection have higher rates of morbidity and would require more hospitalizations compared to adults. Hence the cost of treatment for morbidity, the cost for hospitalization and cost of ART per child per year would be enormous. A study done in US showed that mean total lifetime cost would be $4118, 863 for a HIV infected child.[66] The cost of caring children with HIV infection also justifies the programme to decrease vertical transmission of HIV.

6.9 Birth weights of children born to HIV positive mothers in Kaniyambadi block

The mean birth weight of children born to HIV positive mothers is generally lower than those born to HIV negative mothers. The early termination of pregnancy, intra- uterine growth retardation due to maternal infection and poor diet are among the reasons postulated low birth weight. The social deprivation and lack of resources could be a contributing factor to poor maternal nutrition. The mean birth weight of children born to HIV infected mothers in Kaniyambadi was 2.524 kg with a SD of 0.67 (95% CI 2.274-2.774) as compared to 2.794 kg with an SD of 0.52 (95% CI 2.783- 2.805) among uninfected group. This difference in mean birth weight could be explained by the fact hat majority of them (84.4%) underwent caesarian section at 38 weeks. The velocity of the intrauterine growth was comparable to that of the uninfected group.

The median age for marriage was 21 in 2006 according to the CHAD Health Management and information System (HMIS). The mean maternal age of the HIV exposed children was 24 years with SD of 3.5 and 22.95 years with a SD of 3.59 among the uninfected. The lack of family resources to conduct marriages and the income brought home by an earning daughter may be the reasons for a higher mean maternal age.

6.9.2 Nutritional anthropometry

Rudolf Virchow[78] said “If disease is an expression of individual life under unfavorable circumstances, then epidemics must be indicative of mass disturbances”. The families that are affected by HIV are already exposed to grinding poverty leading to inadequate food, shelter, clean water, and basic medical care or public health and the disease status further exposes them to

malnutrition, disease and death. The inequalities of life bestow them with the double edged sword of HIV and poverty.

In India the prevalence of malnutrition and anemia in the under 5 year population is 65% and 90% respectively.[79] Malnutrition is not just a medical problem, but it stems from social discrimination and inequality. Poverty and under-nutrition go hand in hand. Hence, the current study has chosen 34 children from similar socioeconomic status whose mothers were uninfected to compare the nutritional status of the children born to HIV infected mothers. Using the IAP Classification grade 2 or 3 malnutrition among exposed and unexposed groups were 12 percent and 9.7 percent respectively and the difference was not statistically significant (p-value 0.77). This could be due to regular follow up and a stricter growth monitoring among the exposed households.

The 24 hour recall showed a general deficiency in intake of calories. In both groups, children the daily intake of calories was only 85% of the required. As this was a 24 hour recall it is based on only the diet of the pervious day not taking into consideration days of feasting and fasting. Some of the HIV affected families were receiving supplementation of diet which has enabled the children to be on par with the non HIV affected household.

6.9.3 Morbidity pattern of children born to HIV positive mothers

The morbidity pattern among the HIV exposed and unexposed children were similar. One child was diagnosed with tuberculosis which he got most likely from his father who was on Anti Tuberculosis Treatment (ATT). The study shows that children born to HIV positive mothers have been able to survive inspite of the disadvantaged setting of deprivation and disease.

6.9.4 Infant mortality

The infant mortality is an indicator of the success of child survival interventions in place. The infant mortality rate (IMR) of India varies geographically. The overall infant mortality rate in India was 56 per thousand live births in 2005.[80] The infant mortality is highest among those below the poverty line. Two children from this block who were exposed to maternal HIV infection died during infancy due to acute gastroenteritis before their HIV status could be tested. The IMR among the HIV exposed children in this block was 67 per 1000 live births which is slightly higher than the national average. This could be due to risk of being born in poverty with a higher risk of getting gastrointestinal infections.

6.10 Population Attributable Risks:

To help in prioritization of intervention and resources the population attributable risk is used. According to Newell et al [63] and Spira et al, [60] 60% of HIV positive children will die before their 5^{th} birthday. The under-five mortality rate in India is 85 per 1000 live births. Therefore the relative risk of dying under 5 years of age if infected with HIV would be 7.05. The population attributable risk due to HIV could be calculated using the formula, Pe (OR-1)/ {Pe(OR-1)}+1.

With the current prevalence (Pe) being 0.3 per cent the population, the population attributable risk due to HIV would be 1.7. If we were to have zero cases of HIV then the under 5 mortality would become 83.3 per thousand from its present 85 per thousand. In spite of the economic boom and the progress it has made in science and technology India's health indicators are still not comparable with developed countries. There are various preventable causes of under-five mortality with diarrhoeal

disease, pneumonia, malnutrition, neonatal infections, measles and malaria among the prominent ones. Oral rehydration therapy, water and sanitation, immunization are among various interventions competing with PPTCT to bring down the under five mortality. The population attributable risk for HIV should be considered, keeping the scarce resources available for child survival.

For this program to be replicated it would require a good health infra structure with an efficient system in place. A very high antenatal coverage, high level of screening, follow up and tracking of patients, motivated grass-root level workers, a secondary care center with the backup of a high quality tertiary care unit would ensure a high “pick up” rate of infection and would help prevent vertical transmission by PPTCT interventions. If pick up is poor there is more chance of vertical transmission. Regular follow up of both the infected parents and the child will further improve the outcome of the intervention.

7. LIMITATIONS

1. Sensitivities around HIV related issues makes follow up of cases difficult. 20 mother- child pairs could not be followed up from the inception of the programme.
2. Growth and development of children could not be properly assessed since that part of the study was done in a cross sectional manner that too with a small sample size.
3. As the interview was conducted in-person the reliability of the incomes mentioned by households may not be accurate, and could not be verified by other sources.

8. SUMMARY AND CONCLUSIONS

This study was carried out with the aim of evaluating the effectiveness of the prevention of parent to child transmission of HIV programme (PPTCT) run by CHAD and with the specific objectives of prevalence of HIV among children born to HIV infected mothers, determining the prevalence of HIV among antenatal women in Kaniyambadi and CHAD hospital from May 2002 to December 2006, their compliance to the PPTCT protocol and effectiveness of the intervention programme to prevent vertical transmission of the infection. The study also intended to compare morbidity and nutritional status of children exposed to HIV against control children.

The annual prevalence of HIV in Kaniyambadi was **0.298%** with a range of 0.6% to 0.01% and the prevalence decreased significantly in time, over a five-year period. The prevalence of HIV infection among antenatal women in CHAD hospital was **0.296%.** This prevalence did not change significantly with time. The mean birth weight of HIV exposed children was significant lower compared to the non HIV exposed children (2.524 kg Vs 2.794 kg).

The vertical transmission of HIV after CHADs PPTCT programme was zero **(95% CI 0-9.4%).** The compliance to all four components PPTCT protocols was **71.9 %** (15.6% for 3 components and 6.3 % for 2 and 1 component each).

The children who were HIV exposed had a higher incidence of diarrhea during the period of one month, while the unexposed had higher incidence of respiratory illnesses during the same period.

The nutritional status of the two did not have a significant difference in the prevalence of malnutrition.

The cost of preventing vertical transmission of HIV is justifiable when compared to the cost of treatment of childhood HIV. The interventions currently in place are beneficial and should be strengthened.

This allows us to conclude that in a rural block in South India with a good health infrastructure, with a high antenatal coverage and a high level of screening, PPTCT interventions for HIV would reduce the vertical transmission rate to below ten per cent. A design that provides a closer follow up of patients without compromising on confidentiality can improve compliance to PPTCT interventions.

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LIST OF ABBREVIATION

1. AIDS	Acquired Immuno Deficiency Syndrome
2. AR	Attributable risk
3. ANC	Antenatal Care
4. ARI	Acute Respiratory Illness
5. ART	Antiretroviral therapy
6. ATT	Anti Tuberculosis treatment
7. AZT	Azidothymadine (zidovudine or ZDV)
8. BF	Breast Feeds
9. CDC	Center for Disease Control, Atlanta
10. CMCH	Christian Medical College and Hospital, Vellore
11. CHAD	Community Health and Development
12. CS	Caesarean Section
13. CI	Confidence interval
14. DCT	Direct Coombs test
15. DNA-	Diribose Nucleic Acid
16. ELISA	Enzyme Linked immunosorbent Assay
17. HAART	Highly Activated Anti-Retroviral Therapy
18. HBsAg	Hepatitis B Surface Antigen
19. HDN	Hemolytic Disease of the Newborn
20. HIV	Human Immuno Deficiency virus
21. HMIS	Health Management Information System
22. IAP	Indian Academy of Pediatrics
23. ICT	Indirect Coombs test

24. IMR	Infant Mortality Rate
25. IVDU	Intravenous Drug Users
26. NACO	National AIDS Control Organization
27. NNS	Number Needed to Screen
28. NNT	Number Needed to Treat
29. OI	Opportunistic Infection
30. ORS	Oral Rehydration Therapy
31. OPD	Out Patient Department
32. LRI	Lower Respiratory tract infection
33. LSCS	Lower Segment Caesarian Section
34. PCP	*Pneumocycstic carni(jirovenci)* Pneumonia
35. PCR	Polymerese chain reaction
36. PEM	Protein Energy Malnutrition
37. PHC	primary health center
38. PLWHA	People living with HIV/AIDS
39. PPTCT	Prevention of Parent to Child Transmission
40. PR	Prevalence Ratio
41. STD	Sexually Transmitted Disease
42. TNSAC	Tamil Nadu AIDS Control Society
43. VCTC	Voluntary Counseling and Testing Center
44. UNAIDS	Joint United Nations Programme on HIV/AIDS
45. SD	Standard Deviation
46. WHO	World Health Organization
47. UNICEF	United Nations Children Fund

PARTICIPANT INFORMATION AND CONSENT FORM

STUDY ON THE VERTICAL TRANSMISSION HUMAN IMMUNODEFICIENCY VIRUS BY ACCEPTORS OF THE PREVENTION OF PARENT TO CHILD TRANSMISSION (PPTCT) PROGRAMME

We would like to invite you to participate in a research study. This information is to help you to decide if you would like to participate. Before you agree to take part in this study you should fully understand what is involved. If you have any questions, which are not fully explained in this leaflet, do not hesitate to ask the researcher. You should not agree to take part unless you are completely happy about all the procedures involved. The NACO has developed guidelines, which outline the treatment which all expectant mothers should receive. The purpose of this study is to measure the extent to which the care provided to mothers is in line with these guidelines. The study is being done jointly by Dr Clarence Samuel as part of his thesis. The study is part of a broader study that is being coordinated Community health and Development (CHAD) Department, Christian Medical College.

If you agree to participate in the study, the researcher will ask you a number of questions. You are free to decide whether to answer any question, and you may refuse to answer any of the questions. Your answers will be treated confidentially and the researchers will not discuss them with any staff or patients at the hospital. Your answers will be used in a research report, but this will be done anonymously i.e. your name is not recorded and cannot be linked to you.

This study protocol was submitted to the Research Committee of Christian Medical College and approval has been granted by that committee.

INFORMED CONSENT

I hereby confirm that I have been informed by the investigator, …….……..……. about the nature and conduct of the study.

I am aware that the results of the study will be anonymously processed into a study report. I have had sufficient opportunity to ask questions and declare myself prepared to participate in the study. I am aware that I can withdraw from the study at any time.

Participant's name (Please print) _____

Participant's signature& Date_____

Investigator's name _____

Investigator's signature Date_____

சாட் (**CHAD**) மருத்துவமனையின் கணியம்பாடி வட்டாரத்திற்கான
கர்ப்பகால பராமரிப்புத் திட்டம்

கடந்த 25 வருடங்களுக்கும் மேலாக, சாட் (**CHAD**) மருத்துவமனை, கணியம்பாடி வட்டாரத்து கர்ப்பிணிப் பெண்களுக்கு கர்ப்பகாலப் பராமரிப்பு கொடுத்து வருகின்றது. கடந்த சில வருடங்களில், இரத்தத்தின் மூலம் பரவும் சில நோய்க் கிருமிகள் பிரசவத்தின் போது தாயிடமிருந்து குழந்தைக்கு தொற்றிக் கொள்வதால் குழந்தைக்கு மரணம் அல்லது தீராத நோய் ஏற்படும் நிலைமையைப் பார்த்திருக்கிறோம். மருத்துவத்துறையில் ஏற்பட்டுள்ள முன்னேற்றங்களினால், கர்ப்ப காலத்திலேயே இரத்தப் பரிசோதனை செய்து இத்தகைய கிருமிகளினாலான பாதிப்பு இருந்தால் கண்டறியலாம். இவ்வாறு கிருமிகளினாலான பாதிப்பு இருந்தால், பிறக்கும் குழந்தைக்கு (சிலவேளையில் தாய்மார்களுக்கும் கூட) மருந்து அல்லது தடுப்பூசி கொடுத்து குழந்தைக்கு அந்தக் கிருமிகள் பரவுவதைத் தடுக்கலாம்.

எனவே, சாட் (**CHAD**) மருத்துவமனையின், கணியம்பாடி வட்டாரத்து கர்ப்பிணிப் பெண்களுக்கான கர்ப்பகாலப் பராமரிப்புத் திட்டத்தில், கீழே குறிப்பிடப்பட்டுள்ள மூன்று நோய்களைக் கண்டறியும் இரத்தப் பரிசோதனை இலவசமாகச் செய்யத் திட்டமிடப்பட்டுள்ளது.

1. இரத்தச்சோகை
2. மஞ்சள்காமாலை– பி
3. ஹெச்.ஐ.வி

கர்ப்பமாக உள்ள தாய்க்கு இந்தப் பரிசோதனையில் மஞ்சள்காமாலை– பி அல்லது ஹெச்.ஐ.வி நோய்க்கிருமி இருப்பது கண்டறியப்பட்டால், இந்தச் செய்தியை மருத்துவர் அல்லது நர்ஸ் வேறு எந்த நபருக்கும் தெரிவிக்காமல் அந்தத் தாய்க்கு மட்டும் தெரியப்படுத்துவார்.

அந்த நோய்க் கிருமிகள் குழந்தையைப் பாதிக்காமல் இருக்க தாய்க்கு அல்லது குழந்தை பிறந்தவுடன் குழந்தைக்கு தேவையான மருந்து/ தடுப்பூசி கொடுக்கப்படும்.

மஞ்சள்காமாலை–பி சோதனை மற்றும் ஹெச்.ஐ.வி நோய் கண்டறியும் பரிசோதனைகள் தாய்மார்கள் ஒப்புதல் கொடுத்து, படிவத்தில் கையொப்பமிட்டால் மட்டுமே செய்யப்படும். இந்த சோதனைகளை செய்து கொள்ள மறுத்தாலும் எந்தவித பாகுபாடுமின்றி கர்ப்பகாலப் பராமரிப்பு தொடர்ந்து வழங்கப் படும்.

ஒப்புதல் படிவம்

சாட் (**CHAD**) மருத்துவமனையின், கணியம்பாடி வட்டாரத்து கர்ப்பிணிப் பெண்களுக்கான கர்ப்பகாலப் பராமரிப்புத் திட்டத்தித்தின் கீழ் மருத்துவ கவனிப்பு பெற்று வரும்

திருமதி ..... கணவர் பெயர் .....கிராமம் ..... ஆகிய நான் கீழ்காணும் நோய்களுக்கான இரத்தப் பரிசோதனை செய்ய ஒப்புதல் அளிக்கிறேன்.

1. இரத்தச்சோகை
2. மஞ்சள்காமாலை– பி
3. ஹெச்.ஐ.வி

ஒப்புதல் அளிப்போரின் கையொப்பம்
அல்லது இடது பெருவிரல் அடையாளம்

சாட் (**CHAD**) மருத்துவமனையின்
கர்ப்பகால பராமரிப்புத் திட்டம்

கடந்த 25 வருடங்களுக்கும் மேலாக, சாட் (CHAD) மருத்துவமனை கர்ப்பிணிப் பெண்களுக்கு கர்ப்பகாலப் பராமரிப்பு கொடுத்து வருகின்றது.

கடந்த சில வருடங்களில், இரத்தத்தின் மூலம் பரவும் சில நோய்க் கிருமிகள் பிரசவத்தின் போது தாயிடமிருந்து குழந்தைக்கு தொற்றிக் கொள்வதால் குழந்தைக்கு மரணம் அல்லது தீராத நோய் ஏற்படும் நிலைமையைப் பார்த்திருக்கிறோம். மருத்துவத்துறையில் ஏற்பட்டுள்ள முன்னேற்றங்களினால், கர்ப்ப காலத்திலேயே இரத்தப் பரிசோதனை செய்து இத்தகைய கிருமிகளினாலான பாதிப்பு இருந்தால் கண்டறியலாம். இவ்வாறு கிருமிகளினாலான பாதிப்பு இருந்தால், பிறக்கும் குழந்தைக்கு (சிலவேளையில் தாய்மார்களுக்கும் கூட) மருந்து அல்லது தடுப்பூசி கொடுத்து குழந்தைக்கு அந்தக் கிருமிகள் பரவுவதைத் தடுக்கலாம்.

எனவே, சாட் (CHAD) மருத்துவமனையின் கர்ப்பிணிப் பெண்களுக்கான கர்ப்பகாலப் பராமரிப்புத் திட்டத்தில், ஹெச்.ஐ.வி நோய்கிருமி பாதிப்பு கண்டறியும் இரத்தப் பரிசோதனை இலவசமாகச் செய்யத் திட்டமிடப்பட்டுள்ளது.

கர்ப்பமாக உள்ள தாய்க்கு இந்தப் பரிசோதனையில் ஹெச்.ஐ.வி நோய்க்கிருமி இருப்பது கண்டறியப்பட்டால், இந்தச் செய்தியை மருத்துவர் வேறு எந்த நபருக்கும் தெரிவிக்காமல் அந்தத் தாய்க்கு மட்டும் தெரியப்படுத்தி மேற்கொண்டு செய்ய வேண்டிய ஆலோசனைகள் வழங்கப் படும்.

ஹெச்.ஐ.வி நோய் கண்டறியும் பரிசோதனை தாய்மார்கள் ஒப்புதல் கொடுத்து, படிவத்தில் கையொப்பமிட்டால் மட்டுமே செய்யப்படும். இந்த சோதனைகளை செய்து கொள்ள மறுத்தாலும் எந்தவித பாகுபாடுமின்றி கர்ப்பகாலப் பராமரிப்பு தொடர்ந்து வழங்கப் படும்.

ஒப்புதல் படிவம்

சாட் (CHAD) மருத்துவமனையின் கர்ப்பிணிப் பெண்களுக்கான கர்ப்பகாலப் பராமரிப்புத் திட்டத்தித்தின் கீழ் மருத்துவ கவனிப்பு பெற்று வரும் திருமதி .....

கணவர் பெயர் ..... கிராமம் ..... ஆகிய நான் ஹெச்.ஐ.வி கிருமி பாதிப்பு கண்டறியும் இரத்தப் பரிசோதனை செய்ய ஒப்புதல் அளிக்கிறேன்.

ஒப்புதல் அளிப்போரின் கையொப்பம்
அல்லது இடது பெருவிரல் அடையாளம்